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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-----------------------|---------------------|------------------|
| 10/699,351 | 10/31/2003 | Ronald James Jandacek | 9129L | 2523 |
| 27752 | 7590 | 12/09/2005 | EXAMINER | |
| THE PROCTER & GAMBLE COMPANY INTELLECTUAL PROPERTY DIVISION WINTON HILL TECHNICAL CENTER - BOX 161 6110 CENTER HILL AVENUE CINCINNATI, OH 45224 | | | SPIVACK, PHYLLIS G | |
| | | ART UNIT | | PAPER NUMBER |
| | | 1614 | | |
| DATE MAILED: 12/09/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/699,351 | JANDACEK ET AL. |
| | Examiner | Art Unit |
| | Phyllis G. Spivack | 1614 |

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS,
WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
2a) This action is **FINAL**. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-79 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
5) Claim(s) ____ is/are allowed.
6) Claim(s) ____ is/are rejected.
7) Claim(s) ____ is/are objected to.
8) Claim(s) 1-79 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 37-48, drawn to methods of increasing the viscosity of one or more lipophilic substances present in the gastrointestinal tract comprising administering a stiffening agent and, optionally, a lipase inhibitor, classified in various subclasses of class 514, depending on the stiffening agent and lipase inhibitor contemplated.
- II. Claims 49-58, drawn to methods of treating gastrointestinal distress, fecal urgency, obesity, hyperlipidemia, diarrhea, anal leakage, reducing levels of toxic substances and blood cholesterol levels, inducing satiety, effecting weight loss or weight control, treating Type II diabetes, delaying onset of, or preventing, Type II diabetes, comprising administering a stiffening agent and a lipase inhibitor, classified in various subclasses of class 514, depending on the stiffening agent and lipase inhibitor contemplated.
- III. Claims 71-78, drawn to methods of treating gastrointestinal distress, fecal urgency, obesity, hyperlipidemia, diarrhea, anal leakage, reducing levels of toxic substances and blood cholesterol levels, inducing satiety, effecting weight loss or weight control, treating Type II diabetes, delaying onset of, or preventing, Type II diabetes, comprising administering a stiffening agent, a lipase inhibitor and a non-digestible, non-absorbable, open-celled polymeric foam, and compositions thereto, classified in various subclasses

of classes 424 and 514, depending on the stiffening agent, lipase inhibitor and foam contemplated subclass.

Claims directed to compositions and kits comprising a stiffening agent and a lipase inhibitor, claims 1-36, 59-70 and 79, will be combined with either elected Group I or II *supra*.

The inventions are distinct, each from the other, for the following reasons:

Inventions II and I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects.

The Groups have acquired a separate status in the art by their recognized, divergent subject matter. The searches required for each Group are not co-extensive resulting in an undue burden to the Examiner. Each Group is capable of supporting a separate patent.

Restriction for examination purposes as indicated is proper.

Further, claims 1-79 are generic to a plurality of disclosed patentably distinct species comprising compositions comprising a stiffening agent and a lipase inhibitor. Applicants are required under 35 U.S.C. 121 to elect a single disclosed species of both a stiffening agent and a lipase inhibitor, even though this requirement is traversed.

Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

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case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicants are advised that to be complete, the reply to this requirement must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

A telephone call to the attorney is not required where: 1) the restriction requirement is complex; 2) the application is being prosecuted *pro se*; or, 3) the Examiner knows from past experience that a telephone election will not be made. See MPEP 812.01.

Where the Examiner has required restriction between product and process claims and Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after Final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)*," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply

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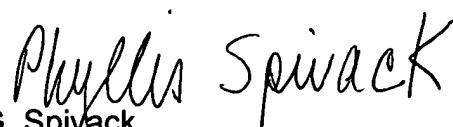
where the Examiner before the patent issues withdraws the restriction requirement. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low can be reached on 591-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 6, 2005


Phyllis G. Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER